UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private
Issuer Pursuant to Rule
13a-16 or 15d-16 of the
Securities Exchange Act
of 1934
For the month of June 2024
Commission File
Number: 001-38283

InflaRx N.V.

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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☐ Form 40-F ☐

INCORPORATION BY REFERENCE

On June 24, 2024, InflaRx N.V. (the "Company") issued a press release titled "InflaRx's GOHIBIC (Vilobelimab) Selected for First BARDA-Sponsored Clinical Trial to Evaluate Novel Host-Directed Therapeutics for Acute Respiratory Distress Syndrome (ARDS)". The Company announced that Biomedical Advanced Research and Development Authority (BARDA) selected GOHIBIC (vilobelimab), an anti-C5a monoclonal antibody authorized under FDA Emergency Use Authorization (EUA) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO), as a host-directed therapeutic candidate for inclusion in a phase 2 platform clinical trial to address acute respiratory distress syndrome (ARDS).

A copy of the press release is attached hereto as Exhibit 99.1, which shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated June 24, 2024

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFLARX N.V.

Date: June 24, 2024

By: /s/ Niels Riedemann

Name: Niels Riedemann
Title: Chief Executive Officer

Exhibit 99.1

InflaRx's GOHIBIC (Vilobelimab) Selected for First BARDA-Sponsored Clinical Trial to Evaluate Novel Host-Directed Therapeutics for Acute Respiratory Distress Syndrome (ARDS)

Jena, Germany, June 24, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics by targeting the complement system, announced today that GOHIBIC (vilobelimab) has been selected by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, as one of three investigational therapies to be assessed in a Phase 2 clinical platform study exploring potential new options for the treatment of acute respiratory distress syndrome (ARDS).

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: "It's a tremendous privilege for InflaRx that BARDA has chosen vilobelimab for inclusion in this pioneering ARDS program. ARDS is one of the most pressing unmet needs in critical care today, with no approved therapy, and we're delighted to expand our dedication to the community with this study made possible by this non-dilutive path to trial participation. Given vilobelimab's potent inhibition of C5a and a host-directed mechanism of action, we believe it has the potential for broader applicability as a potent anti-inflammatory agent in ARDS."

The Phase 2 multicenter, randomized, double-blind, placebo-controlled trial is expected to begin later this year. It is carried out by a global clinical research organization (CRO), PPD Development, LP (a clinical research business of Thermo Fisher Scientific, Inc.), contracted by BARDA. The trial is expected to be conducted at approximately 60 sites in the U.S., with a total target enrollment of 600 hospitalized adults with ARDS. Enrollment will include ARDS due to any etiology other than trauma, large volume aspiration, or transfusion. ARDS severity will be defined prospectively.

Vilobelimab, which will be supplied by InflaRx from its available stock, will be one of three host-directed investigational drugs assessed in this study, with the safety and efficacy of each investigational drug to be studied in its own patient cohort and compared against placebo. Each cohort is expected to enroll 200 patients (100 on investigational drug and 100 on placebo), with both arms in each cohort including standard of care as background therapy.

The primary endpoint will be all-cause mortality at Day 28, with additional efficacy endpoints to include all-cause mortality at additional time periods, days of hospitalization, days in the ICU, daily oxygenation requirements, invasive mechanical ventilation endpoints, as well as other efficacy endpoints and biomarker measures.

This Phase 2 platform study will collect data in order to define subsets of patients with ARDS who may benefit from specific host-directed therapeutics. These data will inform the design of Phase 3 studies and identify a patient subpopulation most likely to benefit from each of the three drug candidates.

About ARDS
ARDS is a life-threatening lung condition with multiple causes, including severe pneumonia and sepsis due to bacterial and viral infections such as influenza and SARS-CoV-2, that leads to high rates of death among hospitalized patients. ARDS is believed to be driven by the body´s immune response to an underlying inflammatory insult, also known as host response, which has been demonstrated to contribute to lung inflammation and tissue damage in multiple pre-clinical studies. Currently, no approved or licensed medications are available to treat ARDS.

About Vilobelimab
Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody, which highly and effectively blocks the biological activity of C5a and demonstrates high selectivity towards its target in human blood. Thus, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism of the innate immune system, which is not the case for molecules blocking C5. In pre-clinical studies, vilobelimab has been shown to control the inflammatory response-driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. In addition to development in COVID-19, vilobelimab is also being developed for various debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum.

About C5a in ARDS
Observational and pre-clinical studies have suggested that the inflammatory host response, the associated tissue damage through endothelial permeability increase, and coagulopathy observed in ARDS are associated with strong complement activation and C5a generation as part of the innate immune response. By targeting the complement component C5a, vilobelimab is believed to block a key mediator of this inflammatory host response and, thus, potentially offers a mechanism of action that may be relevant to organ damage and associated mortality in ARDS. Inhibition of the C5a / C5aR pathway has been demonstrated to be beneficial or lifesaving in various pre-clinical models of viral lung injury and viral sepsis, including studies investigating vilobelimab in influenza, as well as chemically induced lung damage. A recent placebo-controlled, 1:1 randomized, multinational, multicenter study in patients with evidence of SARS-CoV-2 infection who required invasive mechanical ventilation (IMV) or lung replacement therapy (ECMO) has demonstrated a significant 28-day and 60-day survival improvement, which was the basis for an emergency use authorization (EUA) of GOHIBIC (vilobelimab).

Important Information about GOHIBIC (vilobelimab)
Vilobelimab has been granted an EUA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.

The emergency use of GOHIBIC is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.

Vilobelimab is an investigational drug that has not been approved by the FDA for any indication, including for the treatment of COVID-19. There is limited information known about the safety and effectiveness of using GOHIBIC to treat people in the hospital with COVID-19. Please see additional information in the Fact Sheet for Healthcare Providers, Fact Sheet for Patients and Parents/Caregivers and FDA Letter of Authorization on the GOHIBIC website (www.GOHIBIC.com).

Important Safety Information about GOHIBIC (vilobelimab)
There are limited clinical data available for GOHIBIC. Serious and unexpected adverse events (AEs) may occur that have not been previously reported with GOHIBIC use.

GOHIBIC has been associated with an increase of serious infections. In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with GOHIBIC. Hypersensitivity reactions have been observed with GOHIBIC. If a severe hypersensitivity reaction occurs, administration of GOHIBIC should be discontinued and appropriate therapy initiated.

The most common adverse reactions (incidence ≥3%) are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash.

Healthcare providers and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths occurring during GOHIBIC treatment and considered to be potentially attributable to GOHIBIC.

Report side effects to the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. In addition, side effects can be reported to InflaRx at: pvusa@inflarx.de

For the full prescribing information and additional important safety information, please visit www.GOHIBIC.com

About InflaRx N.V.:
InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, InflaRx).

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop, and commercialize highly potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. InflaRx is also developing INF904, an orally administered small molecule inhibitor of C5a-induced signaling via the C5a receptor. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.de.

Contacts:

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue,” among others. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the receptiveness of GOHIBIC (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and the receptiveness of GOHIBIC (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of GOHIBIC (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an EUA and in the future if approved for commercial use in the U.S. or elsewhere; our ability to successfully implement The InflaRx Commitment Program, the success of our future clinical trials for vilobelimab’s treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including PG, and any other product candidates, including INF904, and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and clinical trials of our product candidates and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our MAA submission for vilobelimab and our biologics license application submission for GOHIBIC (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or GOHIBIC (vilobelimab) for any indication; whether the FDA, the EMA or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product GOHIBIC (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading “Risk Factors” in our periodic filings with the SEC. These statements speak only as of the date of this press release and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.